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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,196	LEBEL ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim R jections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 3, 5, 6, 7, 8, 10, 12, 13, 14, 15 and 16 are rejected under 35 U.S.C 102(b) as being anticipated by Tune et al. (USPN 5630710). Tune et al. discloses a medical system, comprising an ambulatory medical device (MD) comprising MD electronic control circuitry (546) that further comprises at least one MD telemetry system (562, 564, 566) and at least one MD processor (542) that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the

medical device is comprises an infusion pump (10), and wherein the CD display device is controlled to show a plurality of infusion parameters simultaneously, and wherein a first portion of the MD telemetry system is incorporated into the MD processor and a second portion of the MD telemetry system is external to the MD processor, or wherein a first portion of the CD telemetry system is incorporated into the CD processor and a second portion of the CD telemetry system is external to the CD processor, wherein (1) the MD electronic control circuitry comprises at least one external MD functional module, other than the second portion of the MD telemetry system, that is external to the MD processor, (2) the CD electronic control circuitry comprises at least one external CD functional module, other than the second portion of the CD telemetry system, that is external to the CD processor, (3) the MD processor comprises an internal MD CPU and at least one other internal MD functional module, or (4) the CD processor comprises an internal CD CPU and at least one other internal CD functional module. (Figures 2,25-30,32-41, and entire reference).

Tune et al. also discloses the communication device with a CD display controlled by at least one CD processor for providing visual feedback to the patient, and wherein the feedback comprises a display of the quantity of a consumable estimated to be remaining in the system (512), wherein the consumable is a drug, and where the medical device wherein infusion parameters can be selected, and where the patient can program (28) there own options into the pump. (Column 3, lines 29-47).

3. Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Causy, III et al. (USPub 2002/0002326).

4. Causy, III et al. discloses an ambulatory medical device and a communication device, wherein the medical device is an infusion pump and MD telemetry system and at least one MD processor that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the medical device is comprises an infusion pump and wherein the CD display device is controlled to show a plurality of infusion parameters simultaneously, and wherein a first portion of the MD telemetry system is incorporated into the MD processor and a second portion of the MD telemetry system is external to the MD processor, or wherein a first portion of the CD telemetry system is incorporated into the CD processor and a second portion of the CD telemetry system is external to the CD processor, wherein (1) the MD electronic control circuitry comprises at least one external MD functional module, other than the second portion of the MD telemetry system, that is external to the MD processor, (2) the CD electronic control circuitry comprises at least one external CD functional module, other than the second portion of the CD telemetry system, that is external to the CD processor, (3) the MD processor comprises an internal MD CPU and at least one other internal MD functional module, or (4) the CD processor comprises an internal CD CPU

and at least one other internal CD functional module. (Figures 1-31 and entire reference).

5. Claims 1, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al. (USPN 2001/0037083). Hartlaub discloses an implantable drug infusion pump with an MD electrical circuit, a processor and a telemetry system, and a communication device, with a CD circuit, a processor and a telemetry system, and where there is a display, that displays feedback on the amount of drugs dosage remaining. (Paragraphs [009], [0010], [0011], [0021], [0023], [0027] and [0038] and the entire reference).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. as applied to claims 1-10 and 12-16 above, and further in view of Er (USPN 6185461).

9. Tune et al. discloses everything as mention above in paragraphs 2, of the claimed invention but fails to disclose wherein the consumable is either (1) battery power remained in a replaceable CD battery in the communication device and a voltage level on the CD battery is graphically depicted with a desired resolution, or (2) battery power remaining in an MD battery in the medical device and a voltage level on the battery is graphically depicted with a desired resolution.

10. Er discloses a controlled system where the display, displays the battery data and battery longevity estimate graph. (Figure 1 and 2 and entire reference).

11. At the time of the invention, it would have been obvious for a person with ordinary skill in the art to combine Tune et al. medical infusion device with Er replacement time indicator device and display, because according to Er, it is highly desirable to predict when a battery will failure so as to make arrangements for the replacement battery. (Column 2, lines 1-9).

Response to Arguments

12. Applicant's arguments filed 10/21/2002 have been fully considered but they are not persuasive.

13. The applicant's argument for Tune et al. is not found persuasive as well as the amendment made to claim 1 to overcome the Tune et al. reference. Tune et al. discloses a medical infusion pump (Ref. # 10), which is the medical device, and a programmer (Ref. # 952) which is the communication device, not the control panel as implied by the applicant in the arguments, therefore the arguments are not drawn to the correct structure in the prior art and are therefore not deemed appropriate and not found persuasive.

14. The applicant's argument of Hartlaub for claims 1 and 4 are not found persuasive, because Hartlaub discloses in paragraph [0038], "a feedback system that discloses a LCD display to provide the patient with an alarm, status and task information...the display would display the drug infusion characteristics and allow the patient to adjust the therapy to provide a more efficient and effective drug treatment." Therefore, it seems inherent to the examiner that the infusion parameters would be displayed simultaneously to the patient, so the patient would be able to observe and comprehend all the data being displayed and make a decision on whether to adjust the treatment parameters allowing the patient to provide a more efficient and effective treatment.

15. The applicant's argument for the 103 rejection is not found persuasive because there is motivation to combine the two references and the feature of claim 11 is taught. Er (USPN 6185461) gives motivation to combine in column 2, lines 1-9, since this medical device is implantable it would be important to predict the failure of the battery and therefore, giving motivation to combine the teachings of Tune et al. with Er. Tune

et al. teaches a medical device and a communication device with a battery and therefore, it would be obvious to use the invention of Er to help in predicating when the battery life of the medical device or the communication device would need to be replaced, as suggested in Er. Er discloses an implantable stimulation device with a battery, with data acquisition and telemetric communication capabilities and an implantable device programmer in the form of a portable computer (Column 2, lines 64 - Column 3, line 16). Er discloses the implantable device programmer is used to display the battery data and optionally the battery longevity prediction graph (Column 7, lines 48-60), therefore, it would be obvious to combine the two reference to obtain the claimed invention because of the motivation of the specification of Er and the fact that Tune et al. is a medical device with a battery, thus determining when the battery needs to be replaced would be an obvious modification in view of Er.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew DeSanto
Art Unit 3763
December 30, 2002

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
12/30/02